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- Descriptive title of the Invention - Cross References to Related Applic - Statement Regarding Fed sponsore		b. Paper Copy (ic	lentical to computer copy)				
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- Background of the Invention - Bnef Summary of the Invention.			PPLICATION PARTS				
- Bnef Description of the Drawings (if - Detailed Description - Claim(s)	filed)	8. 37 C.F.R.§3.73(b) Sta (when there is an assis	gnee) Attorney				
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Address S2 Tenjaran S	treet	- Nasr City					
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Country ESYSYD+	Telephone	72024013478 Fax	+7024021012				
Name (PINIVTYPE) Mohamed Kha	led Mohemme	Registration No. (Attorney/Agent)					

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STATEMENT CLAIMING SM. (37 CFR 1.9(f) & 1.27(b))INI		Docket Number (Optional)
Applicant, Patentee, or Identifier:	Nohamed Khaled Moho	med El Hater
Application or Patent No.:		
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Title: A detector of i	iving fissue strength e	Electrical Fesistance
As a below named inventor, I here for purposes of paying reduced fee	by state that I qualify as an independent invento es to the Patent and Trademark Office describe	or as defined in 37 CFR 1.9(c) d in:
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A DETECTOR OF LIVING TISSUE STRENGTH & ELECTRICAL RESISTANCE & ACTIVITY.

Dr , Mohamed Khaled Mohamed El Hatw(M.D.) Egyptian.
52 Tayaran street Nasr City , Cairo , Egypt.

CROSS REFERENCE TO RELATED APPLICANT&CLINICAL RESEARCH.

"Monitor of living tissue strength & electrical resistance & activity"

Egyptian patent office filed on 22-11-1999 No 1492 .11.1999

Applicant :Dr. Mohamed Khaled Mohamed El Hatw.

BACK GROUND OF THE INVENTION

The old art.

Tissue biopsy is essential for many studies including histopathological, Immunohistological & histochemical studies.

Biopsy can be done by a biopsy needle with a sharp edge to cut the sample & carry it out side the body. In the needle biopsy metal sheath passes an internal metal needle to allow piercing of the overlying tissues.

Defect in the old art.

There is no sure sign that the tip of the needle has arrived to the target tissue this depends partially on the accuracy of the imaging technique & the experience of the operator ,there is also a delay in the diagnostic results.

It is not uncommon that valuable days are lost to receive a pathological report of failure to take the biopsy from the target tissue.

BREIF SUMMARY OF THE INVENTION

This apparatus is used during needle biopsy where it is introduced in the needle biopsy sheath instead of the needle to observe ,measure or record the resistance of the tissues to piercing ,its resistance to passage of electrical current .It also records the electrical activity of the tissue (if any) .These three functions together can help in identification of the nature of the tissue during needle biopsy before the actual cutting of the tissue as well as prediction of the nature of its pathology .

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING

Figure 1 The sensor: The tip of the sensor (1) An electrical isolator (2) The base of the tip of the sensor (3) two side wings (4) metal blade (5) electrical resistance (6) A spiral coil (7) The body of the sensor (8) The base of the sensor (9) The cable: (10) The monitor: Outlet (B) on the base of the monitor (9) The monitor auditory, visual electrical registering unit. (11). The monitor auditory, visual electrical registering unit. (12). The monitor registering unit. (13). The electrical switch (14). A suitable electric source (15)

Figure 2: the sensor with the sheath passing through the skin (1), the subcutaneous tissue (2), the muscles (3), the peinephric fat (4) The renal capsule (5) the renal cortex (6) & the renal medulla (7).

Figure 3a: a diagrammatic presentation of the physical resistance showing higher resistance in the skin (1) & the renal capsule (2).

3b: a diagrammatic presentation of the electrical resistance showing higher resistance in perinephric fat(4).

3c: a diagrammatic presentation of the electrical activity showing higher activity in the muscles (3). Electrical activity of the renal cortex (6) which is variable in different glomerular diseases is also expected.

DETAILED DESCRIPTION OF THE INVENTION.

1-Theoretical background.

The living tissues differ in its consistency, type & density of its cells ,connecting tissues & vascular supply . this variation makes tissues differ in their resistance to passage of a foreign body & resistance to passage of the electrical current. Some of the tissues as the heart & the brain have an evident electrical activity that can be detected from the surface of the skin. Other tissues have less evident electrical activity that can not be detected unless the detector reaches the target tissue.

The idea of this apparatus depends on studying these three characters during taking the biopsy. This will help to ensure arrival of the needle to the target tissue & predict any pathological changes.

2- The structure of the apparatus.

A -The sensor.

- * The shape ,the length & the diameter of the sensor is identical to the internal needle of the renal biopsy needle .This similarity allows its replacement after doing the target function.
- * The tip of the sensor (1) is pointed and connected to the terminal (C) by an isolated wire .that passes in the sensor.
- * An electrical isolator (2) that isolates the tip of the sensor (1) from the base of the tip of the sensor (3).
- * The base of the tip of the sensor (3) is metal & is able to move vertically together with the tip of the sensor (1) & the electrical isolator (2) .It has two side wings (4).

The first wing touches a *metal blade* (5) which is attached to the terminal (B).

The second wing touches a the coil of an *electrical resistance* (6) which is attached to the terminal (A).

- * A spiral coil (7) It is from a non conducting material & it separates the body the sensor (8) from the base of the tip of the sensor (3).
- * The body of the sensor (8) is a metal tube attached to the terminal (D)&is isolated from its internal contents (The electrical resistance (10), the metal blade (5) & the base of the tip of the sensor (3)).

* The base of the sensor (9) it is formed from a non conducting material similar to the base of the original internal biopsy needle. To it the electrical terminals (A,B,C,D) are attached.

B-The cable

* A cable (10) with four isolated wires attach the four terminals of the monitor to the corresponding terminals on the base of the sensor.

C-The monitor.

- * A visual, auditory or electrical intensity or voltage detector (Ammeter or voltmeter) with possibility of adding a registering unit on sensitive paper to monitor & record the physical resistance to entry of the sensor in different tissues while applying a constant pressure.
- * A visual, auditory or electrical intensity or voltage detector (Ammeter or voltmeter) with possibility of adding a registering unit on sensitive paper to monitor & record the electrical resistance to passage of the electrical current in different tissues.
- * The registering unit for the electrical activity of different tissues is similar to that used in the ElectroCardioGagraph (E.C.G.), the Electro EncephaloGraph (E.E.G.) or the ElectroMyoGagraph (E.M.G.). The prementioned devices magnify the intrinsic electrical activity of the tissues & change it into movements of a hot needle over a heat sensitive paper or alternatively express it on the screen.

D-The electrical circuits.

1- A circuit to study the physical resistance.

- Outlet (A) on the base of the sensor (9).
- \blacksquare The connecting wire in the cable (10).
- Outlet (A`) on the monitor.
- The monitor auditory, visual, electrical registering unit.(11).
- The electrical switch (14).
- A suitable electric source (15) that can be tolerated by the body (e.g. not more than 12 Volts)
- Outlet (B) on the monitor.
- The connecting wire in the cable (10).
- Outlet (B) on the base of the sensor (9).
- A wire passing through the body of the sensor (8) connecting the outlet (B) to the metal blade (5).
- \blacksquare The metal blade (5).
- The base of the tip of the sensor (3).
- \blacksquare The electrical resistance (6).
- A wire connecting the electrical resistance (6) to the outlet (A) on the base of the sensor (9).

With increasing physical resistance to the passage of the sensor the tip of the sensor (1), the electrical isolator (2) & the base of the tip of the sensor (3) move vertically together to decrease the electrical resistance. This electrical changes can be detected by the monitor.

2- A circuit to study the electrical resistance.

- Outlet (C) on the base of the sensor (9).
- \blacksquare The connecting wire in the cable (10).
- Outlet (C') on the monitor.
- The monitor auditory, visual, electrical registering unit.(12).
- The electrical switch (14).
- A suitable electric source (15)
- Outlet (B') on the monitor.
- The connecting wire in the cable (10).
- Outlet (B) on the base of the sensor (9).
- A wire passing through the body of the sensor (8) connecting the outlet (B) to the metal blade (5).
- \blacksquare The metal blade (5).
- \blacksquare The base of the tip of the sensor (3).
- The living tissue around the tip of the sensor (1)
- A wire connecting the tip of the sensor (1) to the outlet (C) on the base of the sensor (9).

The electrical resistance to passage of the electrical current differ in the living tissue according to its type & the pathological changes that can be detected by the monitor.

3-A circuit to study the electrical activity.

- Outlet (C) on the base of the sensor (9).
- The connecting wire in the cable (10).

- Outlet (C) on the monitor.
- The monitor registering unit .(13).
- Outlet (D`) on the monitor.
- \blacksquare The connecting wire in the cable (10).
- Outlet (D) on the base of the sensor (9).
- A wire passing through the body of the sensor (8) connecting the outlet (D) to the metal body of the sensor (8)..
- The metal sheath of the biopsy needle (14) which is touching the metal body of the sensor. [but it is not considered as part of the sensor].
- Different living tissues through which the biopsy needle passes & works as the earth terminal to the registering unit .(13).
- The target living tissue for measuring the electrical activity which is in direct contact with the tip of the sensor (1)
- The tip of the sensor (1)
- A wire connecting the tip of the sensor (1) to the outlet (C) on the base of the sensor (9).
- The outlet (C) on the base of the sensor (9).

E- Computerized analysis unit.

After completing the data derived from studying different types of normal & pathological tissues, a computer program can be designed to keep these data.

During tissue biopsy data about the anatomical position of the biopsy can be inserted & the computer program will compare the stored data with the patient's data to give instantaneous diagnosis of the anatomical & pathological data of the tissue at the tip of the sensor.

3-How to use the apparatus?

- 1-The patient is prepared for renal biopsy as usual (positioning ,sterilization, anesthesia & localization of the target tissue or organ by the proper means of imaging).
- 2- Replace the inner needle with a suitable sensor with identical shape & size.
- 3- Switch on the electric switch (14) & apply a constant pressure to push the biopsy needle with the sensor inside in the direction of the target tissue. Observe the monitor reading about the physical & electrical resistance of the tissues while pushing the biopsy needle.
- 4-To verify the nature of the target tissue or the tissue in the way of the needle ,switch off the electric switch (14) & record the intrinsic activity of the tissue surrounding the tip of the sensor (1).
- 5- To cut the target tissue by the Uro-cut biopsy needle model replace the sensor with the original grooved needle, move the sheath up to expose the groove the down to cut the tissue with the sharp metal sheath then withdraw the biopsy needle out with the needle & the tissue inside as usual.
- 6-To cut the target tissue by the Mangini biopsy needle remove the sensor, apply a suction syringe & move the sheath up & down to cut the target tissue.

An expected example during renal biopsy.

- 1- Figure 2: The sensor with the sheath passing through the skin (1), the subcutaneous tissue (2), the muscles (3), the peinephric fat (4) The renal capsule (5) the renal cortex (6) & the renal medulla (7).
- 2-Figure 3a: A diagrammatic presentation of the physical resistance record showing higher resistance in the skin (1) & the renal capsule (2).
- Figure 3b: A diagrammatic presentation of the electrical resistance record showing higher resistance in perinephric fat (4).
- Figure 3c: A diagrammatic presentation of the electrical activity showing higher activity in the muscles (3). Electrical activity of the renal cortex (6) which is variable in different glomerular diseases is also expected.

4- How to get use of the detector?

A-Complete the relevant studies.

- * Studies of living tissues & living animals can verify the characters of healthy living tissues.
- * Noting that the apparatus can work through the biopsy needle no non predetermined human invasive studies will be required.
- * Comparison of the detector findings with data derived from different imaging techniques during biopsy & the results of pathological studies& with the growing data of the electrical disturbances of different disorders (e.g. loss of the glomerular negative charges in Nephrotic Syndrome & recently the electrical disturbances in some hepatic disorders) will help to verify the significance of the detector & feed its computerized analysis units.

B-Manufacture.

- * Supply the sensor as a disposable sterile single use product.
- * The cable & the monitor can be manufactured as permanent devices .Alternatively a small electric lamb or ring can be added to the base of the sensor to be used for detection of physical & electrical resistance.

C-Utilization.

- * The sensors will be consumed with the rate of biopsies taken .
- * The monitors ,cables & data analysis units will be consumed with a number parallel to the number of the medical units performing biopsy

<u>Claims</u>

The first item.

- 1- A detector that can detect ,Monitor & register the resistance of the tissues to piercing ,its resistance to passage of electrical current & the electrical activity of the tissues to help in identification of the nature of the tissue during needle biopsy before the actual cutting of the tissue as well as prediction of the nature of its pathology.
- 3- A visual, auditory or electrical intensity or voltage detector (Ammeter or voltmeter) with possibility of adding a registering unit on sensitive paper for the physical resistance to entry of the sensor in different tissues while applying a constant pressure,
- 4- A visual, auditory or electrical intensity or voltage detector (Ammeter or voltmeter) with possibility of adding a registering unit on sensitive paper for the electrical resistance to passage of the electrical current in different tissues.
- 5- The registering unit for the electrical activity of different tissues similar to that used in the (E.C.G.), (E.E.G.) or (E.M.G.).

The second item.

- 1- The sensor of the detector have the same size & shape of the internal needle of the biopsy needle so that it can be used simultaneously during the biopsy taking without the need to introduce through a different orifice.
- 2- The sensor has an inbuilt changeable resistance that changes according to the resistance faced by the needle during introduction in the tissue with a constant speed.
- 3- The sensor has 2 adjacent points of electrical circuit at a fixed distance.

 The electrical circuit is closed by the living tissues which have different resistance to the electrical current.
- 4- The body of the sensor as passing in the tissue work as an earth electrode (or a separate electrode can be connected to the skin) while the tip of the sensor detect the electrical activity –if any of target or the in way tissues.

The third item.

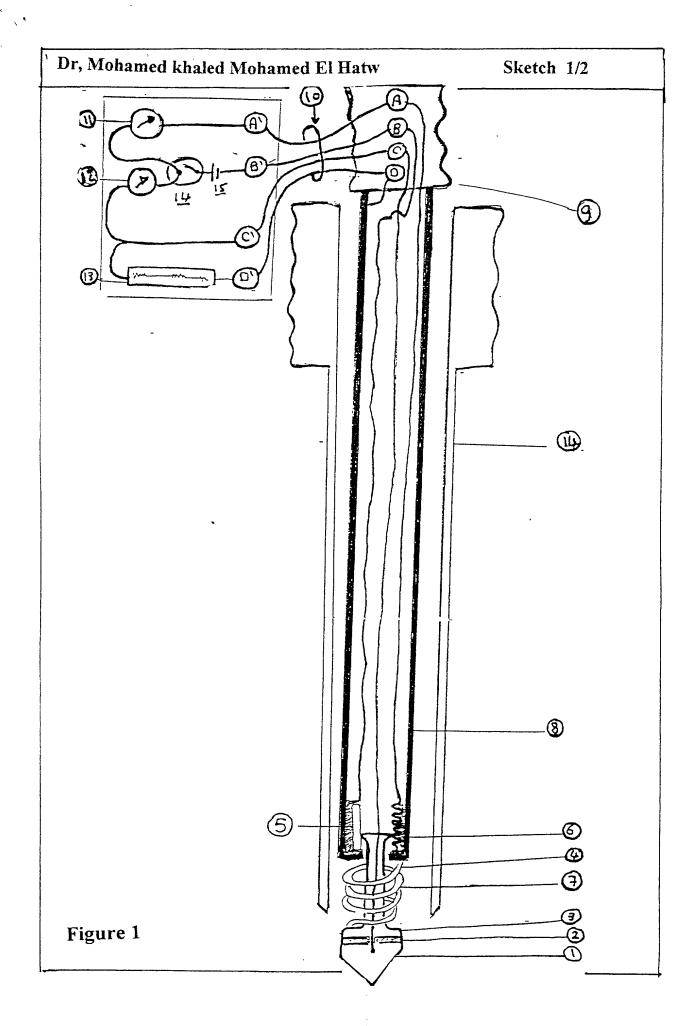
* A Computerized analysis unit to give instantaneous anatomical & pathological diagnostic information of the tissue at the tip of the sensor based on the data derived from the monitor.

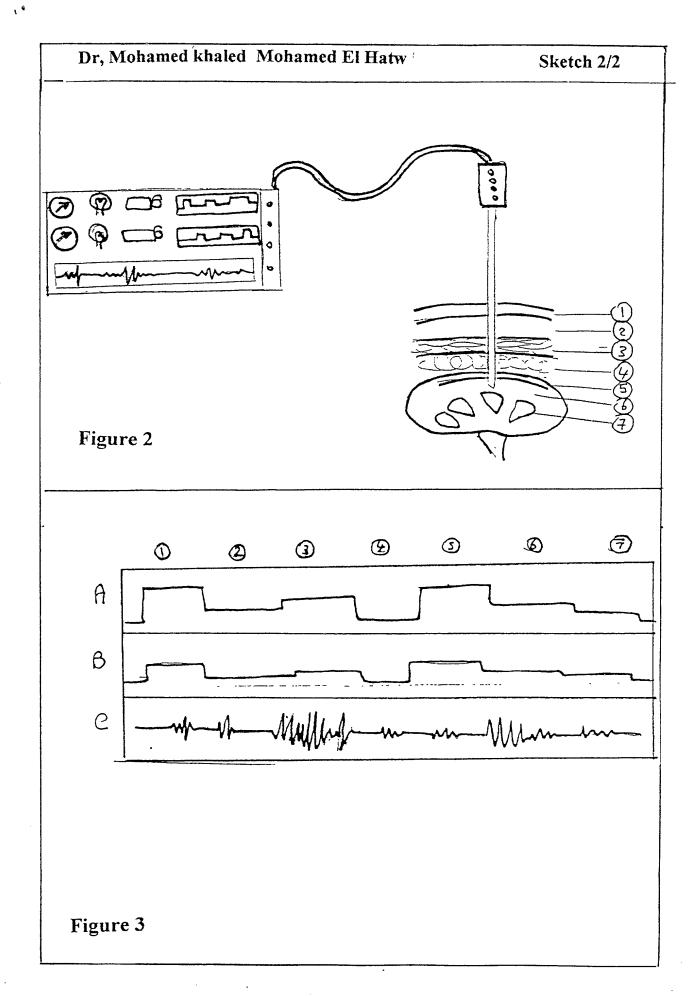
ABSTRACT OF THE DISCLOSURE.

This apparatus observes ,measures or records the resistance of the tissues to piercing ,its resistance to passage of electrical current & its electrical activity.

This apparatus is used during needle biopsy to observe, measure or record these three functions together to help in identification of the nature of the tissue during needle biopsy before the actual cutting of the tissue as well as prediction of the nature of its pathology.

The apparatus is formed of a sensor connected to the monitor by a cable .A data analysis unit can also be added for direct analysis of the patient's data.





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